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FILE 'REGISTRY' ENTERED AT 12:12:16 ON 07 NOV 2006

L1            1 S DONEPEZIL/CN

FILE 'CAPLUS' ENTERED AT 12:12:30 ON 07 NOV 2006

L2            427 S L1 AND ALZHEIM?

L3            51 S L2 AND MMSE

L4            8 S L3 AND SEVERE

=> file registry  
COST IN U.S. DOLLARS  
FULL ESTIMATED COST

SINCE FILE ENTRY	TOTAL SESSION
0.21	0.21

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=> s donepezil/cn  
L1 1 DONEPEZIL/CN

=> file caplus  
COST IN U.S. DOLLARS  
FULL ESTIMATED COST

SINCE FILE ENTRY	TOTAL SESSION
5.20	5.41

FILE 'CAPLUS' ENTERED AT 12:12:30 ON 07 NOV 2006  
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FILE COVERS 1907 - 7 Nov 2006 VOL 145 ISS 20  
FILE LAST UPDATED: 6 Nov 2006 (20061106/ED)

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=> s l1 and alzheim?  
666 L1

L2            41977 ALZHEIM?  
L2            427 L1 AND ALZHEIM?

=> s 12 and MMSE  
L3            419 MMSE  
L3            51 L2 AND MMSE

=> s 13 and severe  
L4            156987 SEVERE  
L4            8 L3 AND SEVERE

=> d 14 1-8 ti

L4            ANSWER 1 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Response to rivastigmine or donepezil in Alzheimer's patients  
with symptoms suggestive of concomitant Lewy body pathology. [Erratum to  
document cited in CA145:117166]

L4            ANSWER 2 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Effect of age on response to rivastigmine or donepezil in patients with  
Alzheimer's disease

L4            ANSWER 3 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Response to rivastigmine or donepezil in Alzheimer's patients  
with symptoms suggestive of concomitant Lewy body pathology

L4            ANSWER 4 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Effects of switching from an AChE inhibitor to a dual AChE-BuChE inhibitor  
in patients with Alzheimer's disease

L4            ANSWER 5 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            An Observational Clinical Study of the Efficacy and Tolerability of  
Donepezil in the Treatment of Alzheimer's Disease

L4            ANSWER 6 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Donepezil and rivastigmine in the treatment of Alzheimer's  
disease: a best-evidence synthesis of the published data on their efficacy  
and cost-effectiveness

L4            ANSWER 7 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Cognitive deficits in Alzheimer's disease: treatment with  
acetylcholinesterase inhibitor agents

L4            ANSWER 8 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Efficacy of acetylcholinesterase inhibitors versus nootropics in  
Alzheimer's disease: A retrospective, longitudinal study

=> d 14 1-8 ti abs bib

L4            ANSWER 1 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI            Response to rivastigmine or donepezil in Alzheimer's patients  
with symptoms suggestive of concomitant Lewy body pathology. [Erratum to  
document cited in CA145:117166]

AB            On page 56, left column, line 5, "192" is incorrect and should read "92".  
AN            2006:1091365 CAPLUS

TI            Response to rivastigmine or donepezil in Alzheimer's patients  
with symptoms suggestive of concomitant Lewy body pathology. [Erratum to  
document cited in CA145:117166]

AU            Touchon, Jacques; Bergman, Howard; Bullock, Roger; Rapatz, Gunter; Nagel,  
Jennifer; Lane, Roger

CS            INSERM 361 CHU, Montpellier, Fr.

SO            Current Medical Research and Opinion (2006), 22(8), 1451  
CODEN: CMROCX; ISSN: 0300-7995

PB LibraPharm Ltd.  
DT Journal; Errata  
LA English

L4 ANSWER 2 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI Effect of age on response to rivastigmine or donepezil in patients with Alzheimer's disease  
AB Background: Younger Alzheimer's disease (AD) patients appear to differ genetically and neuropathol. from older AD patients, and may experience a more aggressive disease course compared with older patients. A randomized trial investigated the efficacy and tolerability of rivastigmine, an inhibitor of acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE), and donepezil, an AChE-selective inhibitor, in patients with AD over a 2-yr period. This retrospective anal. investigated whether younger and older patients showed differential tolerability and efficacy responses to cholinesterase inhibitor treatment. Methods: For the current anal., patients were divided according to age at baseline: those aged < 75 years and those aged ≥ 75 years. Efficacy measures were the Severe Impairment Battery (SIB), Neuropsychiatric Inventory (NPI), Global Deterioration Scale (GDS), Mini-Mental State Examination (MMSE) and the AD Cooperative Study Activities of Daily Living scale (ADCS-ADL). Changes in efficacy parameters and adverse event frequencies were calculated for rivastigmine and donepezil-treated patients in both age groups. Exploratory analyses were also conducted on SIB, ADCS-ADL and NPI in patients who consented to pharmacogenetic testing at baseline. Genotyping of the apolipoprotein E (APOE) ε4 allele and the BuChE K-variant was conducted using the TaqMan assay. Main efficacy analyses were based on an intent-to-treat last observation carried forward (ITT-LOCF) population. Results: Of the 994 patients who received the study drug, 362 (36.4%) were younger than 75 years and 632 (63.6%) were aged 75 years or over. Rivastigmine provided significant benefits in younger patients compared with donepezil on the NPI-10, NPI-12, NPI-D, GDS and ADCS-ADL (all p < 0.05, ITT-LOCF). With the exception of the NPI-D in favor of donepezil (p < 0.05, ITT-LOCF), no significant treatment differences were observed in older patients. Younger patients with two wild-type BuChE alleles had a significantly greater response to rivastigmine than donepezil on the ADCS-ADL (p < 0.01, ITT-LOCF) and SIB (p < 0.05, ITT-LOCF). The most common adverse events were nausea and vomiting and these were more frequent in rivastigmine-treated patients. Conclusion: In this sub group anal., patients younger than 75 years of age showed greater treatment responses to rivastigmine than donepezil. Anal. of response by BuChE genotype suggests that this differential effect may be due to the inhibition of BuChE, in addition to AChE, by rivastigmine.

AN 2006:389254 CAPLUS  
DN 145:306490  
TI Effect of age on response to rivastigmine or donepezil in patients with Alzheimer's disease  
AU Bullock, Roger; Bergman, Howard; Touchon, Jacques; Gambina, Giuseppe; He, Yunsheng; Nagel, Jennifer; Lane, Roger  
CS Kingshill Research Centre, Swindon, UK  
SO Current Medical Research and Opinion (2006), 22(3), 483-494  
CODEN: CMROCX; ISSN: 0300-7995  
PB LibraPharm Ltd.  
DT Journal  
LA English

RE.CNT 33 THERE ARE 33 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 3 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI Response to rivastigmine or donepezil in Alzheimer's patients with symptoms suggestive of concomitant Lewy body pathology  
AB Background: A double-blind randomized trial evaluated the efficacy and tolerability of rivastigmine and donepezil in patients with

Alzheimer's disease (AD) over 2 years. Baseline data indicated that some patients had symptoms suggestive of concomitant Lewy body disease. This retrospective anal. investigated whether AD patients with and without symptoms suggesting concomitant Lewy body pathol. demonstrated different responses to therapy. Methods: AD patients were divided by the presence/absence of symptoms suggestive of concomitant Lewy body disease. These were identified by a concomitant diagnosis of dementia with Lewy bodies and/or use of anti-parkinsonian medication at baseline. Baseline characteristics, demographics, changes on efficacy parameters and adverse event (AE) frequencies were calculated for rivastigmine- and donepezil-treated patients. Efficacy parameters were the Severe Impairment Battery (SIB), Mini-Mental State Examination (MMSE), Global Deterioration Scale (GDS), Neuropsychiatric Inventory (NPI) and AD Cooperative Study Activities of Daily Living scale (ADCS-ADL). Main efficacy analyses were based on an intent-to-treat last observation carried forward (ITT-LOCF) population. Results: Both populations reached mean doses of rivastigmine and donepezil that were within therapeutic ranges. Nine hundred and ninety-four AD patients received study drug, of whom 49 (4.9%) had symptoms suggestive of concomitant Lewy body disease (25 rivastigmine, 24 donepezil). In this subpopulation, changes from baseline after 2 years of treatment with rivastigmine were significantly better than those seen with donepezil on the SIB, MMSE and ADCS-ADL (ANCOVA or Wilcoxon analyses,  $p < 0.05$ , IIT-LOCF). Statistical significance was not maintained in non-ITT-LOCF analyses, except for EP analyses on the SIB and ADCS-ADL (both  $p < 0.05$ ). Rivastigmine also provided significantly better functioning than donepezil in patients without Lewy body pathol., as shown by a significant treatment difference at endpoint on the ADCS-ADL ( $p < 0.05$ , ITT-LOCF; not maintained in non-ITT-LOCF analyses). NPI changes from baseline did not differ significantly between treatment groups. AD patients with symptoms suggestive of concomitant Lewy body disease receiving rivastigmine or donepezil experienced fewer gastrointestinal side effects, leading to fewer discontinuations due to AEs, compared with patients without Lewy body pathol. Conclusion: In this retrospective anal., AD patients who had symptoms suggestive of concomitant Lewy body disease appeared to show greater treatment responses to rivastigmine than to donepezil, and experienced fewer adverse events under either drug, compared with patients without Lewy body pathol.

AN 2006:155973 CAPLUS  
DN 145:117166  
TI Response to rivastigmine or donepezil in Alzheimer's patients with symptoms suggestive of concomitant Lewy body pathology  
AU Touchon, Jacques; Bergman, Howard; Bullock, Roger; Rapatz, Gunter; Nagel, Jennifer; Lane, Roger  
CS INSERM 361, CHU, Montpellier, Fr.  
SO Current Medical Research and Opinion (2006), 22(1), 49-59  
CODEN: CMROCX; ISSN: 0300-7995  
PB LibraPharm Ltd.  
DT Journal  
LA English

RE.CNT 51 THERE ARE 51 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 4 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI Effects of switching from an AChE inhibitor to a dual AChE-BuChE inhibitor in patients with Alzheimer's disease  
AB Cholinesterase (ChE) inhibitors are the only medications approved for the treatment of Alzheimer's disease (AD). The features of ChE inhibitors differ considerably. In addition to acetylcholinesterase (AChE) inhibition, rivastigmine also inhibits butyrylcholinesterase (BuChE), providing dual AChE and BuChE inhibition. An observational study was performed to determine the response in routine clin. practice to switching AD patients to rivastigmine from a selective AChE inhibitor when that treatment no longer delivered a satisfactory clin. response. A

prospective, multicenter, 3-mo observational trial in patients with mild to moderately severe AD (adjusted Mini Mental State Examination [MMSE] score 10-26) deteriorating (at least 2 adjusted MMSE points in last 6 mo) on selective AChE inhibitor treatment. Adjusted MMSE, activities of daily living (ADL) and instrumental activities of daily living (IADL), the Zarit caregiver burden and global function (short Clin. Global Impression of Change, CGIC) scores were noted before the switch and 3 mo after the switch. Two hundred twenty-five patients entered the study. The switches made were from donepezil to rivastigmine (D-R) in 188 patients, galantamine to rivastigmine (G-R) in 33 patients and donepezil to galantamine (D-G) in four patients. Ten patients discontinued due to adverse events and eight for other reasons. More than half of the switches were within 36 h of a patient's first treatment visit. In the D-R and G-R groups, 67.7% and 66.7% of patients responded (CGIC score  $\leq$  4), resp. In non-responders, worsening (CGIC score 5-7) was mild in approx. 80% or more of patients. Adjusted MMSE improved after the switch from both donepezil and galantamine to rivastigmine ( $+0.69 \pm 3.2$ , p = 0.008 and  $+0.6 \pm 1.6$ , p = 0.05, resp.). Mean ADL, IADL and Zarit scores remained stable. The proportion of patients on concomitant antipsychotic therapy diminished by 30.5% and benzodiazepines were discontinued in all patients, except one. AD patients deteriorating on selective AChE inhibitor treatment can benefit from switching to a dual AChE-BuChE inhibitor, such as rivastigmine, in terms of stabilization of disease, improvement in cognitive function and reduction in the burden of concomitant psychoactive treatment. The switch was well tolerated. Confirmation of these results is required in a controlled study.

AN 2006:779 CAPLUS  
DN 144:343421  
TI Effects of switching from an AChE inhibitor to a dual AChE-BuChE inhibitor in patients with Alzheimer's disease  
AU Bartorelli, L.; Giraldi, C.; Saccardo, M.; Cammarata, S.; Bottini, G.; Fasanaro, A. M.; Trequattrini, A.  
CS The Upgrade Study Group, Geriatrics Unit, S. Eugenio Hospital, Rome, Italy  
SO Current Medical Research and Opinion (2005), 21(11), 1809-1817  
CODEN: CMROCX; ISSN: 0300-7995  
PB LibraPharm Ltd.  
DT Journal  
LA English

RE.CNT 31 THERE ARE 31 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 5 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI An Observational Clinical Study of the Efficacy and Tolerability of Donepezil in the Treatment of Alzheimer's Disease  
AB An open-label, observational Post-Marketing Surveillance (PMS) study was undertaken in Germany to examine the efficacy and tolerability of donepezil in routine clin. practice. Alzheimer's disease (AD) patients were treated with donepezil (5 or 10 mg once daily) and observed for a period of approx. 3 mo. Study assessments included the Mini-Mental State Examination (MMSE), the Nurses' Observation Scale for Geriatric Patients (NOSGER), and adverse events (AEs). A total of 2,092 patients (mean age 73.0 yr; mean  $\pm$  SD MMSE score  $17.8 \pm 5.8$ ) were included in the efficacy assessments. MMSE and NOSGER scores showed statistically significant improvements in the total patient population and in the subpopulations with severe AD or AD with concomitant Parkinsonian symptoms (ADPS cohort). AEs were reported in a total of 12% of patients and were mostly due to peripheral cholinergic effects. In this observational PMS study, donepezil was shown to be an effective and well-tolerated therapy in the overall patient population, in patients with severe AD, and in the ADPS cohort.  
AN 2003:200023 CAPLUS  
DN 139:301794  
TI An Observational Clinical Study of the Efficacy and Tolerability of

AU Donepezil in the Treatment of Alzheimer's Disease  
Hager, Klaus; Calabrese, Pasquale; Froelich, Lutz; Goebel, Claus; Berger,  
Frank M.

CS Department of Geriatrics, Henrietten Hospital, Hannover, Germany  
SO Dementia and Geriatric Cognitive Disorders (2003), 15(4), 189-198  
CODEN: DGCDXF; ISSN: 1420-8008

PB S. Karger AG

DT Journal

LA English

RE.CNT 40 THERE ARE 40 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 6 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN

TI Donepezil and rivastigmine in the treatment of Alzheimer's  
disease: a best-evidence synthesis of the published data on their efficacy  
and cost-effectiveness

AB A review. Various drugs have been approved for the treatment of  
Alzheimer's disease (AD) in the United States and Canada,  
including donepezil and rivastigmine, although questions remain as to  
their efficacy, effectiveness, and long-term benefits. The goal of this  
study was to conduct a best-evidence synthesis of data on the efficacy and  
cost-effectiveness of donepezil and rivastigmine in the treatment of AD.  
Relevant published randomized controlled trials (RCTs) and Phase IV  
open-label extension studies (excluding abstrs.) were identified through  
searches of MEDLINE, HealthSTAR, and PsycINFO for the period Jan. 1984 to  
Oct. 2001. The bibliogs. of retrieved articles were searched for addnl.  
publications. For inclusion in the best-evidence synthesis, clin. trials  
had to pass a blinded quality assessment (score  $\geq 5$  on the Jadad  
scale) and use National Institute of Neurol. and Communicative Disease and  
Stroke-Alzheimer's Disease and Related Disorders Association  
diagnostic criteria. Economic studies were selected using National Health  
Service Center for Reviews and Dissemination criteria for reporting critical  
summaries of economic evaluations. Nine RCTs of donepezil and 2 of  
rivastigmine were identified and met inclusion criteria for the  
best-evidence synthesis. Eight donepezil trials and both rivastigmine  
trials included patients with mild AD (Mini-Mental State Examination [  
MMSE] score, 15-27) or moderate AD (MMSE score, 8-14); 1  
donepezil trial included patients with moderate or severe AD (  
MMSE score, 0-7). In the RCTs of donepezil, the mean decrease in  
scores on the Alzheimer's Disease Assessment Scale-cognitive  
sub-scale (ADAS-cog) was greater with active treatment than with placebo  
(lower scores indicate less cognitive deterioration). In the RCTs of  
rivastigmine, ADAS-cog scores decreased over the follow-up period with  
both active treatment and placebo; however, scores decreased more with  
active treatment. Three Phase IV studies of donepezil and 1 Phase IV  
study of rivastigmine were identified. Their results were consistent with  
those of the RCTs. Ten economic studies (7 donepezil, 3 rivastigmine)  
were identified and reviewed. In 4 of the donepezil studies and all 3  
rivastigmine studies, use of the drug cost less than a no-drug strategy.  
The efficacy data indicate that both donepezil and rivastigmine can delay  
cognitive impairment and deterioration in global health for at least 6 mo  
in patients with mild to moderate AD. Patients receiving active treatment  
will have more favorable ADAS-cog scores for at least 6 mo, after which  
their scores will begin to converge with those of patients receiving  
placebo. Differences in methodol., types of direct or indirect costs  
included, and sources of cost data made it difficult to compare and  
synthesize findings of the economic studies; therefore, the  
cost-effectiveness data are inconclusive.

AN 2002:591114 CAPLUS

DN 137:149694

TI Donepezil and rivastigmine in the treatment of Alzheimer's  
disease: a best-evidence synthesis of the published data on their efficacy  
and cost-effectiveness

AU Wolfson, Christina; Oremus, Mark; Shukla, Vijay; Momoli, Franco; Demers,

CS Louise; Perrault, Anne; Moride, Yola  
Centre for Clinical Epidemiology and Community Studies, S.M.B.D. Jewish  
General Hospital, Can.  
SO Clinical Therapeutics (2002), 24(6), 862-886  
CODEN: CLTHDG; ISSN: 0149-2918  
PB Excerpta Medica, Inc.  
DT Journal; General Review  
LA English

RE.CNT 54 THERE ARE 54 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 7 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI Cognitive deficits in Alzheimer's disease: treatment with  
acetylcholinesterase inhibitor agents  
AB The use of acetylcholinesterase (AChE) inhibitors seems to be a promising  
therapeutic strategy against cognitive impairment of Alzheimer's  
disease (AD). We evaluated the safety and the efficacy of two AChE  
inhibitor agents, donepezil and rivastigmine, in the treatment of mild to  
moderately severe AD. Twenty-seven patients were recruited for  
the study. They met DSM-IV criteria for uncomplicated AD and NINCDS-ADRDA  
criteria for probable or possible AD of mild to moderate severity. Mini  
mental state examination (MMSE) scores of 10-21 at screening were  
required. Patients' age was between 53-77 yr. Sixteen patients were  
treated with donepezil, 5 mg/day, and 11 subjects received rivastigmine,  
6-9 mg/day for 30 wk. The rating instruments used were the MMSE  
, the cognitive subscale of the AD assessment scale (ADAS-Cog), and the  
phys. self-maintenance scale (PSMS). The assessment was carried out at  
baseline and at weeks 6, 12, 18, 24, and 30. The results demonstrated the  
pos. effects of these agents on the cognitive and functional pictures in  
patients with mild to moderately severe AD. The adverse events  
related to treatment were generally not troublesome, and were of short  
duration (nausea, vomiting, dizziness, and diarrhea).  
AN 2001:633476 CAPLUS  
DN 135:352692  
TI Cognitive deficits in Alzheimer's disease: treatment with  
acetylcholinesterase inhibitor agents  
AU Fuschillo, C.; La Pia, S.; Campana, F.; Pinto, A.; De Simone, L.  
CS Department of Mental Health, Neuropsychogeriatric Ward of Pollena  
Trocchia, Pollena Trocchia (Napoli), I-80040, Italy  
SO Archives of Gerontology and Geriatrics, Supplement (2001), 7(Cognitive,  
Affective and Behavior Disorders in the Elderly), 151-158  
CODEN: AGGSEU; ISSN: 0924-7947  
PB Elsevier Science Ireland Ltd.  
DT Journal  
LA English

RE.CNT 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 8 OF 8 CAPLUS COPYRIGHT 2006 ACS on STN  
TI Efficacy of acetylcholinesterase inhibitors versus nootropics in  
Alzheimer's disease: A retrospective, longitudinal study  
AB The aim of this study was to investigate the efficacy of nootropics  
(piracetam, aniracetam, nimodipine and dihydroergocristine) vs.  
acetylcholinesterase inhibitors (AChE-Is) (tacrine and donepezil) in the  
treatment of Alzheimer's disease. This is a retrospective study  
of 510 patients with Alzheimer's disease. To determine clin.  
efficacy of treatment, we used the mean change over time in scores for the  
following tests: the Mini-Mental State Examination (MMSE); the  
Cambridge Cognitive Examination for the Elderly; and the Functional Rating  
Scale for Symptoms of Dementia. In all patients and in patients with  
severe Alzheimer's disease (baseline MMSE <  
11), no significant differences were seen in the neuropsychol. test scores  
between the two treatment groups. In patients with moderate dementia  
(baseline MMSE between 11 and 20), however, there was a

significantly greater deterioration, as shown on the CAMCOG scale, after 12 mo' treatment for patients receiving AChE-Is compared with those receiving nootropics (-4.38 for AChE-Is group vs. 1.48 for nootropics group). For patients with mild dementia (baseline MMSE score between 21 and 26), there was a significantly greater deterioration on the MMSE scale for each time-point in the nootropics group compared with the AChE-Is group. In conclusion, we did not find any strong evidence that a difference in efficacy exists between AChE-Is and nootropics in the treatment of Alzheimer's disease.

AN 2001:246165 CAPLUS

DN 135:190250

TI Efficacy of acetylcholinesterase inhibitors versus nootropics in Alzheimer's disease: A retrospective, longitudinal study

AU Tsolaki, M.; Pantazi, T.; Kazis, A.

CS Third Department of Neurology, Aristotle University of Thessaloniki, Thessaloniki, Greece

SO Journal of International Medical Research (2001), 29(1), 28-36  
CODEN: JIMRBV; ISSN: 0300-0605

PB Cambridge Medical Publications Ltd.

DT Journal

LA English

RE.CNT 30 THERE ARE 30 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT